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VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/290,029	04/09/99	BOTTOMLY H	

HM12/0303

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EXAMINER	
EWOLDT, G	

ART UNIT	PAPER NUMBER
1644	5

DATE MAILED: 03/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/290,029	Applicant(s) Bottomly et al.
	Examiner Gerald Ewoldt	Group Art Unit 1644

☒ Responsive to communication(s) filed on 2/22/2000 .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-350* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-350* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Fax Transmittal Form

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Applicant's amendment, filed 2/22/2000, is acknowledged. The amendment to the specification has not been entered because most of the page and line numbers are incorrect. The amendment to the claims has been entered.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-13 and 20-43, drawn to a method of modulating an immune response away from a Th2 response comprising administering a cytokine factor concurrently with exposure to a protein antigen, classified in Class 424, subclasses 85.1, and Class 514, subclass 2.

II. Claims 1-4, 7-13, and 20-43, drawn to a method of modulating an immune response away from a Th2 response comprising administering an inducing agent factor concurrently with exposure to a protein antigen, classified in Class 424, subclasses and 234.1, and Class 514, subclass 2.

III. Claims 1, 7-13, and 20-43, drawn to a method of modulating an immune response away from a Th2 response comprising administering a cytokine factor and an inducing agent factor concurrently with exposure to a protein antigen, classified in Class 424, subclasses 85.1 and 234.1, and Class 514, subclass 2.

IV. Claims 1, 11-13, and 20-47, drawn to a method of modulating an immune response away from a Th1 response comprising administering a cytokine factor concurrently with exposure to a protein antigen, classified in Class 424, subclasses 85.1, and Class 514, subclass 2.

V. Claims 1, 11-13, 20-45, and 48-49, drawn to a method of modulating an immune response away from a Th1 response comprising administering an inducing agent factor concurrently with exposure to a protein antigen, classified in Class 424, subclasses and 234.1, and Class 514, subclass 2.

VI. Claims 1, 11-13, and 20-49, drawn to a method of modulating an immune response away from a Th1 response comprising administering a cytokine factor and an inducing agent factor concurrently with exposure to a protein antigen, classified in Class 424, subclasses 85.1 and 234.1, and Class 514, subclass 2.

VII. Claims 1-43, drawn to a method of modulating an immune response away from a Th2 response comprising administering a cytokine factor concurrently with exposure to a nucleic acid, classified in Class 424, subclasses 85.1, and Class 514, subclass 44.

VIII. Claims 1-4 and 7-43, drawn to a method of modulating an immune response away from a Th2 response comprising administering an inducing agent factor concurrently with exposure to a nucleic acid, classified in Class 424, subclasses and 234.1, and Class 514, subclass 44.

IX. Claims 1 and 7-43, drawn to a method of modulating an immune response away from a Th2 response comprising administering a cytokine factor and an inducing agent factor concurrently with exposure to a nucleic acid, classified in Class 424, subclasses 85.1 and 234.1, and Class 514, subclass 44.

X. Claims 1, 11-15, and 20-47, drawn to a method of modulating an immune response away from a Th1 response comprising administering a cytokine factor concurrently with exposure to a nucleic acid, classified in Class 424, subclasses 85.1, and Class 514, subclass 44.

XI. Claims 1, 11-15, 20-45, and 48-49, drawn to a method of modulating an immune response away from a Th1 response comprising administering an inducing agent factor concurrently with exposure to a nucleic acid, classified in Class 424, subclasses and 234.1, and Class 514, subclass 44.

XII. Claims 1, 11-15, and 20-49, drawn to a method of modulating an immune response away from a Th1 response comprising administering a cytokine factor and an inducing agent factor concurrently with exposure to a nucleic acid, classified in Class 424, subclasses 85.1 and 234.1, and Class 514, subclass 44.

XIII. Claims 50-61, 63-69, 79-98, 102-114, 122-127, 129, 136-157, 160-165, 167-176, and 184-193, drawn to a method of modulating an immune response away from a Th2 response comprising isolating one or more pAPC from an individual and exposing said pAPC to a cytokine factor concurrently with exposure to a protein antigen then administering said cells to a subject, classified in Class 424, subclasses 85.1, and Class 514, subclass 2.

XIV. Claims 50-55, 60-61, 63-69, 79-98, 102-112, 115-117, 122-123, 125-127, 129, 136-157, 160-176, and 184-193, drawn to a method of modulating an immune response away from a Th2 response comprising isolating one or more pAPC from an individual and exposing said pAPC to an inducing agent factor concurrently with exposure to a protein antigen then administering said cells to a subject, classified in Class 424, subclasses and 234.1, and Class 514, subclass 2.

XV. Claims 50-61, 63-64, 70-73, 79-101, 106-112, 118-119, 122-127, 129, 136-159, 194-200, 202-210, and 218-226, drawn to a method of modulating an immune response away from a Th1 response comprising isolating one or more pAPC from an individual and exposing said pAPC to a cytokine factor concurrently with exposure to a protein antigen then administering said cells to a subject, classified in Class 424, subclasses 85.1, and Class 514, subclass 2.

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XVII. Claims 50-69, 79-98, 102-114, 122-128, 136-157, 160-165, 167-176, and 184-192, drawn to a method of modulating an immune response away from a Th2 response comprising isolating one or more pAPC from an individual and exposing said pAPC to a cytokine factor concurrently with exposure to a nucleic acid then administering said cells to a subject, classified in Class 424, subclasses 85.1, and Class 514, subclass 44.

XVIII. Claims 50-55, 60-69, 79-98, 102-112, 115-117, 122-123, 125-127, 128, 136-157, 160-176, and 184-192, drawn to a method of modulating an immune response away from a Th2 response comprising isolating one or more pAPC from an individual and exposing said pAPC to an inducing agent factor concurrently with exposure to a nucleic acid then administering said cells to a subject, classified in Class 424, subclasses and 234.1, and Class 514, subclass 44.

XIX. Claims 50-64, 70-101, 106-112, 118-119, 122-128, 136-159, 194-200, 202-211, and 218-226, drawn to a method of modulating an immune response away from a Th1 response comprising isolating one or more pAPC from an individual and exposing said pAPC to a cytokine factor concurrently with exposure to a nucleic acid then administering said cells to a subject, classified in Class 424, subclasses 85.1, and Class 514, subclass 44.

XX. Claims 50-55, 60-64, 70-101, 106-112, 120-123, 125-128, 136-159, 194-211, and 218-226, drawn to a method of modulating an immune response away from a Th2 response comprising isolating one or more pAPC from an individual and exposing said pAPC to an inducing agent factor concurrently with exposure to a nucleic acid then administering said cells to a subject, classified in Class 424, subclasses and 234.1, and Class 514, subclass 44.

XXI. Claims 74, 79-98, 102-114, 122-127, 129-130, 136-157, 160-165, 167-176, 178 and 184-193, drawn to a method of modulating an immune response away from a Th2 response comprising isolating one or more pAPC from an individual and exposing said pAPC to a nucleic acid encoding a cytokine factor concurrently with exposure to a protein antigen then administering said cells to a subject, classified in Class 424, subclasses 85.1, and Class 514, subclass 2.

XXII. Claims 74, 79-98, 102-112, 115-117, 122-123, 125-127, 129-130, 136-157, 160-176, 178, and 184-193, drawn to a method of modulating an immune response away from a Th2 response comprising isolating one or more pAPC from an individual and exposing said pAPC to a nucleic acid encoding an inducing agent factor concurrently with exposure to a protein antigen then administering said cells to a subject, classified in Class 424, subclasses and 234.1, and Class 514, subclass 2.

XXIII. Claims 74, 79-101, 106-112, 118-119, 122-127, 129-130, 136-159, 194-200, 202-210, 212, and 218-226, drawn to a method of modulating an immune response away from a Th1 response comprising isolating one or more pAPC from an individual and exposing said pAPC to a nucleic acid encoding a cytokine factor concurrently with exposure to a protein antigen then administering said cells to a subject, classified in Class 424, subclasses 85.1, and Class 514, subclass 2.

XXIV. Claims 74, 79-101, 106-112, 120-123, 125-127, 129-130, 136-159, 194-210, 212, and 218-226, drawn to a method of modulating an immune response away from a Th2 response comprising isolating one or more pAPC from an individual and exposing said pAPC to a nucleic acid encoding an inducing agent factor concurrently with exposure to a protein antigen then administering said cells to a subject, classified in Class 424, subclasses and 234.1, and Class 514, subclass 2.

XXV. Claims 74-98, 102-114, 122-157, 160-165, 167-176, and 178-192, drawn to a method of modulating an immune response away from a Th2 response comprising isolating one or more pAPC from an individual and exposing said pAPC to a nucleic acid encoding a cytokine factor concurrently with exposure to a nucleic acid then administering said cells to a subject, classified in Class 424, subclasses 85.1, and Class 514, subclass 44.

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XXVII. Claims 74-101, 106-112, 118-119, 122-159, 194-200, and 202-226, drawn to a method of modulating an immune response away from a Th1 response comprising isolating one or more pAPC from an individual and exposing said pAPC to a nucleic acid encoding a cytokine factor concurrently with exposure to a nucleic acid then administering said cells to a subject, classified in Class 424, subclasses 85.1, and Class 514, subclass 44.

XXVIII. Claims 74-101, 106-112, 120-123, 125-159, and 194-2226, drawn to a method of modulating an immune response away from a Th2 response comprising isolating one or more pAPC from an individual and exposing said pAPC to a nucleic acid encoding an inducing agent factor concurrently with exposure to a nucleic acid then administering said cells to a subject, classified in Class 424, subclasses and 234.1, and Class 514, subclass 44.

XXIX. Claims 227-229, 233, 237-260, and 269-271, drawn to a composition for modulating an immune response by stimulating a Th1 response comprising a cytokine factor and a protein antigen, classified in Class 424, subclasses 85.1, and Class 514, subclass 2.

XXX. Claims 227, 232-234, 237-258, 261-263, and 269-271, drawn to a composition for modulating an immune response by stimulating a Th1 response comprising an inducing agent factor and a protein antigen, classified in Class 424, subclasses and 234.1, and Class 514, subclass 2.

XXXI. Claims 227, 237-258, and 269-271, drawn to a composition for modulating an immune response by stimulating a Th1 response comprising a nucleic acid encoding an inducing agent factor and a protein antigen, classified in Class 424, subclasses and 234.1, and Class 514, subclass 44.

XXXII. Claims 227-229, 233-234, 237-260, and 269-271, drawn to a composition for modulating an immune response by stimulating a Th1 response comprising a cytokine factor and a nucleic acid encoding a protein antigen, classified in Class 424, subclasses 85.1, and Class 514, subclass 44.

XXXIII. Claims 227, 232-234, 237-258, 261-263, and 269-271, drawn to a composition for modulating an immune response by stimulating a Th1 response comprising an inducing agent factor and a nucleic acid encoding a protein antigen, classified in Class 424, subclasses and 234.1, and Class 514, subclass 44.

XXXIV. Claims 227, 237-258, and 269-281, drawn to a composition for modulating an immune response by stimulating a Th1 response comprising a nucleic acid encoding an inducing agent factor and a nucleic acid encoding a protein antigen, classified in Class 514, subclass 44.

XXXV. Claims 227, 230-231, 233, 237-258, 264-265, and 269-271, drawn to a composition for modulating an immune response by stimulating a Th2 response comprising a cytokine factor and a protein antigen, classified in Class 424, subclasses 85.1, and Class 514, subclass 2.

XXXVI. Claims 227, 233-258, 266-271, drawn to a composition for modulating an immune response by stimulating a Th2 response comprising an inducing agent factor and a protein antigen, classified in Class 424, subclasses and 234.1, and Class 514, subclass 2.

XXXVII. Claims 227, 237-258, and 269-271, drawn to a composition for modulating an immune response by stimulating a Th2 response comprising a nucleic acid encoding an inducing agent factor and a protein antigen, classified in Class 424, subclasses and 234.1, and Class 514, subclass 44.

XXXVIII. Claims 227, 230-231, 237-258, 264-265, and 269-271, drawn to a composition for modulating an immune response by stimulating a Th2 response comprising a cytokine factor and a nucleic acid encoding a protein antigen, classified in Class 424, subclasses 85.1, and Class 514, subclass 44.

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XXXX. Claims 227, 237-258, and 269-281, drawn to a composition for modulating an immune response by stimulating a Th2 response comprising a nucleic acid encoding an inducing agent factor and a nucleic acid encoding a protein antigen, classified in Class 514, subclass 44.

The inventions are distinct, each from the other because:

4. Inventions I-XXVIII are different methods requiring different reagents, affecting different cell types, and have different endpoints. Therefore they are patentably distinct.

5. Inventions XXIX-XXXX are different products. They have different ingredients with different structures and different modes of action. Therefore they are patentably distinct.

6. Because these inventions are distinct for the reasons given above and the search required for any of the Groups I-XXXX is not required for any other Group, restriction for examination purposes as indicated is proper.

7. Irrespective of whichever Group Applicant should elect, Applicant is further required under 35 U.S.C. § 121 to:

1) Elect:

A) A **specific** method of modulating an immune response comprising steps using a **specific** "factor", a **specific** antigen, and a **specific** "targeting agent" (if any Group I-XII is elected).

B) A **specific** method of modulating an immune response comprising steps using a **specific** "factor", a **specific** antigen, a **specific** **specific** "targeting agent", a **specific** pAPC, and a **specific** "encapsulating device" (if any Group XIII-XXVIII is elected).

C) A **specific** compositon for modulating an immune response comprising a **specific** antigen, a **specific** "targeting agent", a **specific** pAPC, a **specific** pAPC "factor", and a **specific** "encapsulating device" (if any Group XXIX-XXXX is elected).

2) List **all** Claims readable thereon including those subsequently added. Currently Claims 1, 50, 109, 160, 194 and 227 are generic.

8. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. The different compositions for modulating an immune response, or methods of modulating an immune system using said compositions, are independent and patentably distinct because different factors, such as cytokines and bacterial extracts, have different structures and functional effects. Different antigens, such as blood group antigens and myelin basic protein, also have different structures and functional effects. Different targeting agents, such as a mannose receptor and an Fc receptor have different structures and bind different ligands. Different encapsulating devices, such as a protein capsule and a liposome, have different structures and different targets. Different pAPCs, such as dendritic cells and B cells, have different functions in different compartments and present antigen in different contexts.

Therefore the species of Groups I-XXXX are independent and the methods of Groups I-XXVIII and the compositions of Groups XXIX-XXXX are patentable over one another.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Gerald Ewoldt, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
February 16, 2000

CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP ~~1800~~ 1640

RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

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TO EXAMINER: GERALD EWOLDT

ART UNIT: *1644*

SERIAL NUMBER: 09/290,029

FAX/TELECOPIER NUMBER: **(703) 305-3704**

PLEASE NOTE: THIS FACSIMILE NUMBER IS TO BE USED ONLY FOR RESPONSES TO RESTRICTIONS.

COMMENTS: _____

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IN COMPLIANCE WITH 1096 OG 30, THE FILING DATE ACCORDED EACH OFFICIAL FAX TRANSMISSION WILL BE DETERMINED BY THE FAX MACHINE DATE STAMP FOUND ON THE LAST PAGE OF THE TRANSMISSION, UNLESS THAT DATE IS A SATURDAY, SUNDAY, OR FEDERAL HOLIDAY WITHIN THE DISTRICT OF COLUMBIA, IN WHICH CASE THE OFFICIAL DATE OF RECEIPT WILL BE THE NEXT BUSINESS DAY.